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**Attachment 4**

510(K) Summary of Safety and Effectiveness

This 510(K) Summary of Safety and Effectiveness for the Q-YAG™ Nd:YAG Laser System is submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and follows the Office of Device Evaluation (ODE) guidance concerning the organization and content of a 510(K) summary.

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| Applicant: | Palomar Medical Technologies, Inc. |
| Address: | 82 Cambridge St.<br>Burlington, MA 01803 |
| Contact Person: | Marcy Moore |
| Telephone: | 919-363-2432 |
| Preparation Date: | 11/25/02 |
| Device Trade Name: | Palomar Q-YAG™ Nd:YAG Laser System |
| Common Name: | Q:Switched Nd:YAG |
| Classification Name: | Laser surgical instrument for use in General and Plastic Surgery and in Dermatology<br>(see: 21 CFR 878-4810).<br>Product Code: GEX<br>Panel: 79 |
| Legally-Marketed Predicate Device: | ThermoLase SoftLight<br>K971207 |
| System Description: | The complete system consists of a power supply unit, a cooling unit, a foot switch, and the hand piece that connects the laser unit and cooling unit using an umbilical cord. In standard use, the hand piece is held against the treatment area and the light pulse is delivered when the foot switch and hand switch is depressed. Laser parameters and other system features are controlled from a display panel located on the front of the power supply unit. |

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| Intended Use of the Device: | The Palomar Q-YAG™ is indicated for laser skin resurfacing with or without adjuvant preparation. |
| Performance Data: | The differences in the specifications of the laser and the predicate device do not result in different performance or raise new questions of safety or efficacy. |
| Conclusion: | Based on the foregoing, the Palomar Q-YAG™ Nd:YAG Laser System is substantially equivalent to the legally-marketed claimed predicate device, i.e., the Thermolase SoftLight. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 7 2003

Palomar Medical Technologies, Inc.
Marcy Moore
Manager of Clinical Studies
131 Kelekent Lane
Cary, North Carolina 27511

Re: K023967
Trade/Device Name: Palomar Q-YAG™ Nd:YAG Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 27, 2002
Received: November 29, 2002

Dear Ms. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## INDICATION FOR USE STATEMENT

510(K) Number: K023967

Device Name: Palomar Q-YAG™ Nd:YAG Laser System

Indications for Use:

The Palomar Q-YAG™ Nd:YAG laser system is indicated at the 1064 nm wavelength for skin resurfacing with or without adjuvant preparation.

(Please do not write below this line - Continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K023967